and directed Gilead's sales and marketing staff to use this additional information to promote Viread, in violation of FDA rules and regulations.

104. In addition, CW3 stated that although Viread's FDA-approved package insert was updated regularly throughout her/his four-year tenure with Gilead, by the time the package insert was updated, the Therapeutic Specialists had moved on to discussing other unapproved data from ongoing studies. For example, if 24-week or 48-week data became FDA approved, the Company's sales staff would be out promoting and selling Viread based on unapproved 144-week data. CW3 stated this unapproved data from ongoing study results was used to market Viread off-label. When she/he worked as a Therapeutic Specialist, CW3 recalled receiving such unapproved study updates from Studies 902, 903, and 907.

105. Along with the other Confidential Witnesses, CW1 and CW2 witnessed first-hand, along with Defendants Martin, Milligan, and Perry, among others, how the "wink and nod" technique would operate to provide Gilead's sales and marketing team with off-label information to boost Viread sales and gain an unfair advantage over competitors. For example, at meetings, such as the Arizona National Meeting, the sales and marketing staff would first attend large meetings during which Gilead executives and clinical personnel presented off-label data. Then, the sales and marketing team would break down into smaller groups for additional meetings. It was during these smaller meetings that CW1 and CW2 and other Confidential Witnesses received specific off-label promotional material instructions, as described herein. Typically, the sales and marketing team would then reconvene, where they were told to sell Viread based on what they had been told in the smaller meetings, without any specific mention of the instructions issued. In this manner, Gilead could simply present the off-label material and then quietly instruct, behind closed doors, its sales and marketing people to sell off-label, while continuing to cover itself with a paper trail at the larger meetings. As CW4 recalled, Defendants tried to cover their tracks, knowing that outward directives to promote Viread for off-label use would raise compliance issues.

106. Both CW1 and CW2 recall that at the Arizona National Meeting, Michael Miller ("Miller"), Gilead's Chief Virologist, made presentations to Gilead's sales and marketing team

regarding off-label Viread clinical data such as instances of HIV resistance. Among others, Defendants Martin, Milligan, and Perry were in attendance.

107. CW1 and CW2 also recall that, while at the Arizona National Meeting, Fletcher, Gilead's Director of Marketing, instructed Gilead's sales team to steer their Viread sales presentations toward off-label information. Among others, Defendants Martin, Perry, Milligan, and Bischofberger were present at this meeting.

108. Defendants knew that their off-label marketing violated FDA rules and regulations. In fact, the FDA concluded that, while attending the December 2001 41st Interscience Conference on Antimicrobial Agents and Chemotherapy in Chicago, Gilead made false and misleading statements about Viread at its promotional exhibit, including statements regarding the risks and efficacy associated with Viread. As explained below, on March 14, 2002, once it learned of Defendants' misleading promotional campaign, the FDA/DDMAC issued a letter to Defendants condemning their actions (hereinafter the "Untitled FDA Letter"). *See* Exhibit D attached hereto (a true and correct copy of the Untitled FDA Letter). ***According to CW1, CW2, and CW5, the statements condemned by the FDA/DDMAC letter were made by Defendant Martin. In fact, according to CW1 and CW2, it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter***. CW5 recalled Martin had been promoting Viread as a miracle drug, and that Martin was doing so because Gilead needed to overcome the perception in the medical community that Viread was like Gilead's previous HIV drugs and would likely cause kidney damage. In essence, Martin was promoting Viread as having a safety profile better than was actually the case in a bid to overcome the negative connotation sometimes associated with Gilead's HIV therapeutics in the market in the 2001 to 2002 timeframe. Indeed, CW8 also confirmed that Martin would refer to Viread as a miracle product all the time at meetings.

109. On January 30-31, 2002, Gilead held a regional sales and marketing meeting in Chicago (the "January 2002 Mid-West Regional Meeting") to address slow Viread sales in the Mid-West region. CW1 recalls that during that meeting, DelloStritto, Meyers, Kristin Bennet ("Bennet"), Gilead's Director of Training, and Mark Bernstein ("Bernstein"), one of Gilead's Medical Science Liaisons, made it clear to Gilead's Mid-West Therapeutic Specialists (as had been done at the

Arizona National Meeting) that it was both acceptable and encouraged to violate FDA regulations and market Viread with off-label information without first obtaining a doctor's request for such information. According to CW1, Gilead echoed that same instruction at several national meetings attended by the Individual Defendants. CW2 attended a similar meeting in Dallas, Texas (the "2002 Dallas Regional Meeting").

110. At the January 2002 Mid-West Regional Meeting, CW1 recalls Gilead providing updates regarding Viread's HIV resistance profile and the progression of Studies 902 and 907. Gilead designed Study 902 to test the long-term efficacy of Viread in patients with HIV who were already on other HIV/AIDS medications for at least eight weeks prior to enrollment in the study. The primary objective of Study 907, on the other hand, was to evaluate the safety and efficacy of Viread in a large population.

111. The primary object of Study 902 was to evaluate the long-term safety of three different doses of Viread and to confirm the results of previous efficacy tests. The selection criteria depended upon the amount of the HIV virus present in the patient's body and what medication the patient was currently taking. The 189 patients in Study 902 had to already be on HIV drug therapy consisting of no more than four active medications for at least eight weeks prior to enrollment. Other requirements related to overall health including renal, hepatic, and hematologic function. Gilead included this study in the FDA Briefing document, ***but any results that were not approved by the FDA, or any updated results from on-going patient studies, were off-label.***

112. Thus, providing Gilead's sales and marketing staff members with updated, off-label information on Study 902 would permit them to opine on the long-term safety of Viread in patients also taking other HIV/AIDS medications, despite the fact that the FDA had not approved such updated information. According to CW1 and CW2, long-term safety data for any HIV medication is invaluable for marketing such drugs because many HIV drugs are new to the marketplace, creating an inherent lack of long-term data. This perspective was also expressed by several other Confidential Witnesses, including CW5. The ability, or in Gilead's case, the audacity, to present such data would provide a clear advantage in the marketplace, resulting in increased demand for Viread.

113. Specifically, at the January 2002 Mid-West Regional Meeting, presenters discussed unproven and non-FDA approved theories of how Viread can allegedly remain dormant in a healthy cell, laying in wait for the HIV virus to attack the cell. CW1 recalls that Gilead used this off-label information to give Gilead's sales and marketing team an advantage over its competition and boost Viread sales. According to CW2, presenters at the 2002 Dallas Regional Meeting discussed the same theoretical and unapproved off-label materials.

114. In addition, prior to the January 2002 Mid-West Regional Meeting, Meyers, Bennet, and DelloStritto specifically instructed CW1 to teach other Gilead Therapeutic Specialists and marketing employees how to successfully market Viread using this off-label information.

115. Specifically, CW1 was told that because she/he was skilled at manipulating potential Viread purchasers into discussing issues which required the disclosure of off-label materials, thus creating openings for discussion of off-label materials, CW1 was selected to teach other salespeople how to lead customers (*i.e.*, physicians and other medical professionals) to these openings. CW1 did as she/he was instructed to do out of fear of losing her/his job.

116. Consequently, in addition to receiving additional off-label information from Gilead executives, CW1 trained no fewer than five other Therapeutic Specialists how to successfully market Viread using off-label information. CW1 recalls that Meyers was present while CW1 instructed other Therapeutic Specialists on how to market off-label. In fact, after all was said and done, Meyers even complimented CW1's off-label training techniques.

117. On February 11-13, 2002, Gilead held a Field Advisory Committee meeting at the New York offices of Harrison & Star, Gilead's advertising agency (the "February 2002 Field Advisory Committee Meeting"). CW1 attended this meeting along with a select group of Viread national sales and marketing team members to discuss Viread sales and sales practices with members of Gilead's executive departments. The attendees included CW1, five other Therapeutic Specialists, Fletcher, Gilead's Director of Marketing until the summer of 2002, and John Windt ("Windt"), Gilead's Associate Director of Marketing. CW1 recalls that at the meeting, Fletcher and Windt, as Gilead marketing executives, asked the Therapeutic Specialists how they were using off-label information in the field to promote and sell Viread. In response, the Therapeutic Specialists reported

their experiences utilizing off-label materials to promote Viread and increase their sales of Viread. As a result, CW1 is able to confirm that her/his experiences of marketing Viread with off-label information were the same as Therapeutic Specialists from all regions of the country. Likewise, it is reasonable to infer that other Therapeutic Specialists throughout the United States materially increased their Viread sales as a result of the use of off-label marketing materials. Indeed, as discussed more fully below, 85% to 95% of CW1's Viread sales were caused by off-label marketing. CW2's sales were similarly impacted, including during the Class Period. CW1 and CW2 also have stated that as a result of certain "high density" HIV/AIDS population areas, such as New York City, Boston, and Washington D.C., the range of Gilead's sales of Viread overall that were caused by off-label marketing was between 75% and 95%.[3] CW6, who sold Viread in the New York City area, stated that "easily 70%" of her/his Viread sales were attributable to off-label sales to treatment naïve patients, and that the Company also encouraged off-label sales to Hepatitis patients. It is therefore reasonable for this Court to infer that between 75% and 95% of all Viread sales during the Class Period were caused by the use of off-label marketing, as discussed more fully below.

118. As at other Gilead meetings, the use of off-label information in the sale and promotion of Viread was specifically discussed and encouraged at the February 2002 Field Advisory Committee Meeting, even in the presence of Gilead senior executives such as Fletcher and Windt. At the time, Fletcher was Gilead's Director of Marketing and reported to Weisbrich, Gilead's Vice-President of Sales and Marketing, who, in turn, reported to Inouye and Defendant Martin. Windt reported to Fletcher.

119. On February 20-22, 2002, Gilead held another regional sales and marketing meeting in Chicago (the "February 2002 Mid-West Regional Meeting"). Again, Gilead presenters told the

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[3] CW1 states that in extremely large United States HIV markets, such as New York City, Boston, and Washington D.C., the percentage of sales caused by off-label marketing was likely to be below 75% because physicians would be more familiar with the existence of AIDS drugs and the higher incidences of HIV make it easier for sales representatives to sell larger quantities of Viread (there was less of a need, and less pressure, to market off-label). As a corollary, CW1 states that in non-HIV intensive markets, the percentage of off-label Viread sales would fall in the 85% to 95% range because it was harder to sell vast quantities of Viread, and thus resort to off-label tactics was necessary to meet sales goals.

sales and marketing staff that it was acceptable and encouraged to promote Viread using off-label information. As at previous Gilead meetings, CW1 was specifically provided with off-label information for Viread, and was encouraged to use that information, in violation of FDA rules and regulations, to make Viread sales. CW1 recalls that during the February 2002 Mid-West Regional Meeting, Miller, Gilead's Chief Virologist, updated the off-label Viread information. Specifically, Miller discussed Viread's resistance profile in treatment "experienced" versus treatment "naïve" patients, as part of Gilead's ongoing, illegal efforts to sell Viread to treatment naïve patients, despite the fact the FDA had not yet approved Viread for such use. At around the same time, CW2 attended a Houston regional meeting wherein Gilead presenters discussed similar substantive materials and gave the same instructions regarding the use of off-label materials.

120. According to CW1 and CW2, at the time of the February 2002 Mid-West Regional Meeting and Houston regional meeting, Gilead was testing Viread's levels of success in patients already using HIV/AIDS medication (*i.e.*, the experienced indication) and comparing those results to the level of success in patients who had never used HIV/AIDS medication (*i.e.*, the naïve indication). Gilead planned to use this off-label data to expand the indication (use) of Viread into treatment of naïve patients, thus increasing sales, despite the fact that the FDA had approved no data at that time showing that Viread worked as a first-line therapy in treatment naïve patients. Similarly, CW4 stated despite the lack of approval for Viread for treatment naïve HIV patients, marketing and selling Viread to treatment naïve patients was always a key component of the Company's strategy for Viread. CW6 echoed this experience, stating ***at least 70%*** of her/his Viread sales were off-label to treatment naïve patients, and that if Therapeutic Specialists did not sell Viread as a first-line therapy, they would be fired.

121. As described above, one month later the March 14, 2002 Untitled FDA Letter advised Gilead that its representatives' false and misleading promotional activities violated the Federal Food, Drug, and Cosmetic Act. *See* Exhibit D.

122. According to the Untitled FDA Letter, Gilead had falsely and misleadingly promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was "extremely well-tolerated" despite the fact that its boxed warning and Package Labeling advised to the contrary. The

FDA stated that Gilead further violated the Federal Food, Drug, and Cosmetic Act by misrepresenting Viread's safety profile. Specifically, Gilead minimized Viread's black boxed warning (part of the Package Labeling) and suggested that its drug was safer than what was demonstrated by scientific evidence. In addition, the FDA stated that Gilead "engaged in false and misleading promotional activities about the efficacy of Viread," claimed that Viread was "approved for a broad indication" and characterized Viread as a "miracle drug," even though the FDA had not determined the clinical benefit of Viread in HIV patients.

123. The Untitled FDA Letter ordered Gilead to "immediately cease making such violative statements" and required Gilead to submit a written response to the DDMAC describing its intent and plans to comply with the DDMAC's directives and identifying the specific date upon which Gilead planned to discontinue its illegal promotional activities.

124. On March 21, 2002, Gilead responded to the Untitled FDA Letter, assuring the DDMAC that its illegal promotional activities would cease (Gilead's letter stated, in pertinent part, that its letter "constitute[d] Gilead's commitment to ensure that future violative statements are not made in the promotion of Viread"). As described below, Gilead's "commitment" did not prevent it from continuing its off label marketing scheme.

B. Defendants Continue to Falsely Promote Viread During 2002, Notwithstanding their FDA Violations

125. Nevertheless, Gilead and the Individual Defendants either specifically directed Gilead's sales force to engage in the false, misleading, and illegal promotional and marketing activities described by the Confidential Witnesses proscribed by the Untitled FDA Letter, or, at the very least, knew of the ongoing improper and illegal promotional and marketing activities but, with a "wink and a nod," allowed them to take place, continue, and ratified them. According to CW1, Gilead made no marketing adjustments as a result of the Untitled FDA Letter. Further, both CW1 and CW2 understood (and believed it was company-wide knowledge) that it was Defendant Martin's comments that resulted in the letter. Similarly, CW8 recalls that Martin referred to Viread as a miracle product and espoused off-label uses for Viread. Indeed, Gilead's marketing misconduct continued (and, in actuality, increased) over time, including into the Second Quarter 2003.

126. As a result of the specific activities identified, criticized, and rejected in the Untitled FDA Letter, Gilead continued planting the seeds of fraud that ultimately contributed to the artificial inflation of its sales of Viread.

127. The Untitled FDA Letter did not deter Gilead from continuing its campaign of false, improper, and illegal marketing and promotional activities, despite the fact that Gilead assured the DDMAC and the FDA that its illegal activities would cease. Instead, Gilead's lies continued over time, including into the Second Quarter 2003.

128. According to CW1, in the Second Quarter of 2002, sales representatives were instructed to develop relationships with gastroenterologists in order to off-label market Viread for the treatment of Hepatitis B infection. CW1 received this instruction from her/his regional director. In addition, the off-label use of Viread to treat Hepatitis B infection was discussed at sales meetings by both Gilead's marketing staff and the Vice President of Sales, Meyers. CW2 confirmed that she/he was instructed to and did attempt to begin to develop relationships with gastroenterologists in order to induce them to prescribe Viread.

129. Similarly, CW4 recalled that Gilead promoted Viread for a Hepatitis B indication. She/he stated that Gilead had the data to support Viread for a Hepatitis B indication, but had not received FDA approval for that indication. Likewise, CW3, CW5, CW6, and CW7 stated Viread was marketed and sold off-label as a treatment for Hepatitis B. As set forth above and in more detail below, CW5 even stated that during April 2003, Gilead presented a slide to its sales force instructing them to market directly to Hepatitis B doctors.

130. During the Class Period, however, Gilead never received FDA approval to sell or market, in any way, Viread as an approved treatment for Hepatitis B infection (regardless of whether the patient was also infected with HIV). In an effort to broaden the indication for Viread, and materially increase sales, Gilead nevertheless funded a small "open-label" patient study of Viread in HIV-1 and Hepatitis B virus co-infected individuals to demonstrate that Viread may work as a treatment option for Hepatitis B infected patients. But, Gilead's study did not meet the FDA's requirements for demonstrating the safety or efficacy of a Viread-based therapy for treating Hepatitis B infection – the study only had 20 patients.

131. As a matter of fact, at all relevant times, the FDA had a black box warning concerning the use of Viread to treat Hepatitis B in HIV co-infected patients. The warning stated that use of Viread by co-infected patients is dangerous because there is a risk of severe acute exacerbations of the Hepatitis B infection in patients when Viread is discontinued in such patients. Indeed, HIV positive patients must rotate their usage of antiretroviral drugs, such as Viread, over time to prevent the emergence of "HIV resistance" – a term used to describe the HIV virus' ability to mutate over time so as to render drugs, such as Viread, ineffective. Thus, according to Viread's FDA-imposed black box warning, an HIV and Hepatitis B co-infected patient who stops taking Viread due to HIV resistance may, as a result, suffer even more severe, acute liver damage from exacerbations of Hepatitis B infection. Because of these documented problems, Defendants' off-label marketing potentially and significantly endangered the very patients to whom the drug was being improperly marketed.

132. Despite all of this, CW4 stated that it was common sentiment at Gilead that the Company did not even need to seek FDA approval for Viread as a Hepatitis B treatment option because it would be used for such purposes even without FDA approval. Among other things, CW4 stated this was because of the Company's marketing of Viread for such off-label uses. CW4 stated that 100% of sales of Viread for a Hepatitis B indication were the result of off-label marketing. CW6 likewise stated the Company's Medical Science Liaisons were indicating such a dual use for Viread, akin to killing two birds with one stone, to treat Hepatitis B and HIV. She/he recalled that the Company's Medical Sciences Liaisons accompanied her/him on sales calls all the time because they purportedly had the scientific credibility to discuss off-label uses with physicians during sales presentations. CW6 stated that was why the Company hired medical doctors to be Medical Science Liaisons. She/he believed the Medical Science Liaisons were used to help sell Viread for off-label uses. CW6 stated that this seemed to be the norm at Gilead. Similarly, CW5 stated the Company's Medical Science Liaisons were used as an off-label marketing tool and often operated in a sales capacity during CW5's tenure at Gilead. CW5 recalled that Bill Guyer ("Guyer") was a Gilead Medical Science Liaison who regularly acted in a sales role and disseminated off-label information

about Viread. CW5 stated that in approximately 2003, Guyer presented data to the incoming HIV Therapeutic Specialists about Viread's use as a treatment for Hepatitis B co-infected patients.

133. On April 17-18, 2002, Gilead held a regional sales and marketing meeting in Chicago to update its Mid-West sales force with additional off-label information. CW1 attended this meeting, and specifically recalls Gilead presenters once again providing the Mid-West sales and marketing team with updated off-label Viread information and encouraging them to use the materials to illegally promote Viread.

134. On May 6, 2002, CW1 attended a meeting of Gilead's Field Advisory Committee in New York (the "May 2002 Field Advisory Committee Meeting"). Fletcher and Inouye also attended this meeting.

135. During the May 2002 Field Advisory Committee Meeting, CW1, along with a handful of other Therapeutic Specialists from around the country, described to Gilead's marketing officers and executives, including Inouye and Fletcher, how they were promoting Viread in all regions. Specifically, CW1 recalls discussions regarding how the sales and marketing staff was promoting Viread with off-label information. In fact, the attendees specifically discussed off-label clinical information that recently had been provided to physicians at a conference in Seattle, Washington. Again, CW1 and the other members of the Field Advisory Committee were updated with additional off-label information that Gilead would be presenting at an upcoming July 7-12, 2002, international AIDS/HIV conference in Barcelona, Spain. The recurring discussions between and among Therapeutic Specialists during Field Marketing Advisory Committee meetings are a powerful backdrop for CW1's estimate that 75% to 95% of all Viread sales were caused by off-label marketing as well as CW2's estimate that 85% to 90% of all Viread sales during the Class Period were a direct result of off-label marketing and CW6's estimate that at least 70% of her/his Viread sales were off-label. These facts provide additional support for the Court drawing an inference that, like CW1, CW2, and CW6, all Gilead sales people materially increased sales of Viread as a direct result of off-label marketing.

136. On May 14-17, 2002, Gilead held a sales and marketing meeting in Los Angeles, California for four sales regions of the country including Chicago, Dallas, Los Angeles, and San

Francisco (the "2002 Los Angeles Regional Meeting"). At the meeting, Gilead presenters provided the sales and marketing staff from these four regions with additional off-label information to use in the promotion and sale of Viread and off-label clinical and theoretical information that was going to be presented at the upcoming July 2002 international HIV/AIDS conference in Barcelona, Spain. CW1 and CW2 attended the meeting and recall that Defendants Meyers, Perry, and Martin were present when presenters directed Gilead's sales and marketing people to use off-label information.

137. Specifically, CW1 recalls discussions at the 2002 Los Angeles Regional Meeting regarding Viread's efficacy in the treatment of Hepatitis B infection. CW1 and the other attendees were instructed to market Viread for the treatment of HIV and Hepatitis B infection in order to boost sales, despite the fact that Viread was only approved for HIV.

138. Thus, as with all of its other meetings, at the 2002 Los Angeles Regional Meeting Gilead continued to inundate its sales and marketing staff with off-label information, while encouraging, expecting, and directing them to use it to promote Viread in violation of FDA rules and regulations. According to CW1 and CW2, the practice of providing off-label materials to boost sales began with and ran to the highest levels of Gilead's hierarchy, including Defendants Martin, Bischofberger, Perry, Milligan, and Lee, among others. CW3, CW4, and CW5, among others, also stated the Company's practice of providing its sales force with off-label materials ran from the top-down at Gilead.

139. On July 15, 2002, CW1 raised concerns with DelloStritto in Chicago, Illinois regarding the use of off-label information. CW1 recalls that DelloStritto wanted more sales from the Mid-West territory and told CW1 that if CW1 used more off-label data, CW1 would get more sales.

140. Gilead's senior management continuously and repeatedly instructed Gilead's sales force to utilize off-label materials in order to sell greater quantities of Viread. For example, in mid-2002, Bill Strong ("Strong"), Gilead's Region Trainer for the Dallas Region, accompanied CW2 on a number of sales calls in order to provide CW2 with "additional training" if necessary. After observing CW2's performance, Strong attempted to train CW2 to increase his focus on and utilization of off-label materials to more effectively market Viread. Among the off-label materials Strong emphasized were materials regarding Viread's efficacy, safety risks, and dosages. In

response, CW2 informed Strong that he believed it was improper for CW2 to follow Strong's directive and utilize off-label materials to market Viread. Nevertheless, CW2 was forced to utilize off-label materials in order to make sales and keep her/his job.

141. On July 15, 2002, Kaiser and Robert Wallace ("Wallace"), one of Gilead's Medical Science Liaisons, summoned CW2 to a meeting at the Atlanta airport Westin Hotel. During this meeting, Kaiser and Wallace instructed CW2 that, instead of selling Viread using the materials in the Package Labeling, he or she should sell Viread using the "theory of HIV" and the "theories behind the benefits of using Viread," despite the fact that none of these "theories" were approved by the FDA and that many were unsupported by scientific studies. CW2 again expressed her/his reluctance to use off-label materials to market Viread.

142. In fact, as a result of her/his meeting with Kaiser and Wallace, Meyers summoned CW2 to a meeting at the Bellagio Hotel coffee shop in Las Vegas, Nevada (CW2 and Meyers were both in Las Vegas for Gilead's September 9-13, 2002 national meeting (the "Las Vegas National Meeting"), to discuss her/his position on off-label marketing. During this meeting, Meyers expressed his exasperation at CW2's refusal to maximize her/his use of Viread off-label marketing materials. Meyers told CW2 that if CW2 failed to fit the mold of a Gilead Therapeutic Specialist, CW2 would not be able to make her/his sales numbers. Despite CW2's continued reluctance to use off-label materials to market Viread, CW2 assured Meyers that she/he could do her/his job and work with both Kaiser and Wallace. In short, CW2 was given no choice but to follow Defendants' directive and utilize off-label marketing materials to sell Viread. As set forth below, despite CW2's reservations, CW2 did off-label market and CW2 states that 85% to 95% of her/his sales, including those sales during the Class Period, were caused by CW2's use of off-label marketing tactics.

143. While attending the Las Vegas National Meeting, CW1 and CW2 recall that Inouye and Defendants Milligan, Perry, Bischofberger, and Martin were also present. Once again, Gilead's presenters provided the marketing and sales team with substantial amounts of off-label information to use to sell Viread by differentiating it from the competition. Specifically, Gilead's presenters discussed clinical data, not yet approved by the FDA, which had been presented at the July 2002

international HIV/AIDS conference in Barcelona, Spain, as well as other new theories on Viread's resistance profile.

144. CW1 and CW2 believe that without making improper, off-label distinctions as part of its standard sales practice, Gilead would not have had such rapid success in the promotion of Viread.

145. On October 10-11, 2002, CW1 attended another meeting of the Field Advisory Committee at Gilead's headquarters in Foster City, California. Meyers, Kelly Seither, Gilead's Associate Director of Marketing, and Inouye, as well as other Therapeutic Specialists from around the country attended the meeting. At the meeting, Gilead presenters provided CW1 and other Therapeutic Specialists with updated information regarding Study 903, which had just reached the three-year mark. The presenters told them how to push Viread with additional results from Study 903, results not found in the Package Labeling and not approved by the FDA. The incomplete Study 903, testing Viread as a first-line therapy in treatment naïve patients, was again being used by Defendants to increase Viread sales through off-label marketing.

146. On October 17, 2002, CW1 attended a regional meeting of the Mid-West Viread sales and marketing team in Chicago, Illinois. As at other national and regional meetings, Gilead presenters provided CW1 and the other members of the sales team with off-label information and encouraged them to use such information to sell Viread. Likewise, CW2 attended a regional meeting in Dallas and was given the same directives.

147. On November 1, 2002, CW1 attended a national liver disease meeting in Boston, Massachusetts. Numerous representatives from Gilead attended the meeting, including Defendants Martin and Perry, and Meyers. Because Viread was not approved to treat Hepatitis B infection, the only reason Gilead executives would have attended this meeting was to make contact with, and attempt to influence, liver specialists to prescribe Viread. During the meeting, on November 2, 2002, CW1 met with Meyers to discuss the off-label marketing of Viread, and the prevalence of Gilead's false, misleading, and improper sales practices. Rather than alleviate CW1's concerns, Meyers instructed CW1 to use every piece of available off-label information to promote Viread, to sell Viread with the information presented at the national and regional meetings, and to do as CW1 was told.

148. After working as a Therapeutic Specialist, CW3 was promoted to the position of Manager of Training in approximately late 2002. As a Trainer, CW3's role was to write-up materials for use by the Company's sales force in their presentations to doctors that contained both information about Viread that was approved by the FDA and unapproved information from recent conferences and ongoing studies. For example, CW3 was tasked with getting materials updated and distributed to regional trainers.

149. CW3 stated Gilead's training department, however, was being used to deliver marketing's message. Because the Company's marketing department could not overtly tell the sales force to sell off-label, Defendants' sales strategy for Viread entailed the incorporation of unapproved study data being placed in training materials that were then used by Therapeutic Specialists in sales calls in their respective territories. In other words, Defendants used the Company's official training department and materials to deliver off-label information to Gilead's sales force – putting the Company's official stamp of approval on the use of off-label information to illegally sell Viread. In basic terms, CW3 stated it was the Company's strategy to provide off-label materials to sales team members for promotional purposes.

150. CW3 noted the Gilead HIV Therapeutic Specialist training materials, including those throughout the Class Period, contained a great deal of off-label information, and that these training materials were provided to the Therapeutic Specialists not just to keep them apprised of recent events and results of studies in the industry, but also ***specifically*** for use as talking points with the doctors on which they called to sell Viread. As an example, CW3 pointed to posters from conferences that were reduced in size, color-copied, and distributed to the Therapeutic Specialists for use in their sales calls. For instance, posters presented at the Interscience Conference on Retroviruses and Opportunistic Infections ("CROI") regarding the most recent study results for Viread were distributed as part of the marketing materials provided to the Gilead sales team for Viread. These documents were commonly known to the sales team members as "backgrounders." As set forth above, several other Confidential Witnesses, such as CW5, confirmed off-label materials were provided to the sales force through training materials, binders, and "poster books."

151. In addition, CW3 recalled that Meyers, Gilead's Vice President of U.S. Sales, directed CW3 to write training materials for Viread's sales force that contained bullet points layered with both FDA-approved and unapproved, recently-released study data. At Meyers' direction, CW3 prepared "abstracts" on the results of recent studies of Viread for off-label indications and documents that contained bullet points that highlighted potential uses of Viread – including for off-label purposes. The inclusion of unapproved data in the Therapeutic Specialist training materials and talking points was concerning to CW3 because the Therapeutic Specialists were being ***encouraged to engage their existing and potential clients in off-label discussion regarding Viread using the information contained in the documents they received***. She/he recalled the unapproved data basically expounded on the approved studies and widened the indications for Viread during the Class Period.

152. Similarly, the sales scripts CW3 prepared were presented and provided to Therapeutic Specialists at national and regional sales meetings. While CW3 drafted the training materials containing off-label data that were used by the Therapeutic Specialists to market and sell Viread for off-label indications during the Class Period, CW3 did not present such data. Rather, when the results of new studies were presented to the sales force, the presentations were made by the "Clinical Science" staff. For example, CW3 stated Defendant Bischofberger made presentations about the study data to the sales organization, including providing details on some of the information that CW3 incorporated in the training materials. Also, Chief Virologist Miller was Gilead's "resistance" specialist, and made presentations to the sales force regarding off-label study data related to resistance issues, such as the issue with the "K65R mutation."

153. On top of the national and regional meetings discussed herein and below, CW3 states there were internal Gilead weekly meetings from at least late 2002 until at least January 2005 – throughout the Class Period. Held in conference rooms at the Company's Foster City, California headquarters, the meetings were conducted to discuss the provision of off-label materials to HIV sales force. These meetings were attended by marketing and training department heads, sales directors, CW3, and Meyers was brought in at the end of each meeting.

154. At these weekly meetings, there was a debate about whether to continue to provide off-label data to the Therapeutic Specialists, and this represented a point of contention within the Company in the period leading up to and throughout the Class Period. CW3 stated there were essentially two disparate opinions about the distribution of off-label materials to the sales force, which included those who thought the sales force should receive no off-label materials and those who believed it necessary to provide the sales force with off-label data and information. CW3 stated the Company's "Clinical Staff" did not want the sales representatives to have any off-label documentation. By contrast, the marketing and sales departments and personnel desired that the Therapeutic Specialists received regular updates about the status of studies on Viread and updates on findings from such studies that could and were used in discussions with practitioners in violation of FDA rules. CW3 stated Meyers supported the latter notion – namely that Therapeutic Specialists should continue to receive off-label marketing materials, and Meyers directed the provision of such materials be done through the training department. Thus, the systematic use of illegal, off-label marketing at Gilead was not the by-product of rogue salespeople or a handful of careless Therapeutic Specialists who did not know the difference between right and wrong. Rather, the decision to provide the sales force with off-label information for illegal marketing and sales activities was deliberate, came from the highest levels within the Company, and was uniformly applied on a Company-wide basis through training materials given to the entire Viread sales staff.

155. For example, the documents included in the training binders that Gilead and CW3 created included the Viread package inserts, package inserts for competing drugs, tables with side-by-side comparisons of each, and other "approved training material," and off-label materials. CW3 stated that before her/his promotion in late 2002, there were some disclaimers on the documents submitted to the sales force indicating they were off-label materials not to be used for promotional purposes, but this was not the norm. As such, CW3 stated these materials were used to sell and promote Viread off-label by Therapeutic Specialists.

156. By the time CW3 was promoted in late 2002, internal discussions within the Company regarding the distribution of off-label marketing materials to the HIV Therapeutic Specialists had reached the point where senior management acknowledged it was inappropriate for

the Company's marketing department to disseminate such information to the sales force. Thus, the training department became the sacrificial lamb through which Defendants would accomplish their fraudulent scheme of off-label marketing. CW3 stated that she/he became part of the "wink and nod" process of supplying the Therapeutic Specialists with the information they utilized to market and sell Viread off-label.

157. Despite being tapped with delivering Defendants' off-label message to the sales force through training materials, CW3 tried in vain to implement a certain standard of ethics. For example, beginning in 2003, she/he implemented a practice of watermarking documents that were distributed by the training organization. The watermarks were initially small and on the side or margins of the documents – which enabled them to be easily copied with the watermarking removed. Throughout the remainder of her/his tenure, however, CW3 changed her/his practices and made the watermarks larger and posted diagonally across the entire page. The watermarks read "not for promotional use."

158. CW3's efforts to implement controls to prevent illegal off-label marketing were met with stern objections and often circumvented at high-ranking levels without consequence. Meyers and the sales managers objected to CW3's efforts to implement such controls. Indeed, members of the sales team were able to get from other sources clean copies of the same documents watermarked by CW3. CW3 stated the Company's actions appeared to be a deliberate effort to circumvent any limitations on the provision of off-label information to Therapeutic Specialists for sales and marketing purposes. For example, CW3 knew that the Therapeutic Specialists had copies of non-watermarked documents because the Regional Trainers informed CW3 that their subordinate sales personnel already had non-watermarked copies of the documents. CW3 believed the Therapeutic Specialists were using the non-watermarked copies of the documents in discussions with HIV practitioners and stated there were no processes in place at Gilead during the Class Period to prevent the use of such non-watermarked materials for selling purposes. For example, CW6 stated that although many off-label materials were stamped "For Educational Purposes," those designations could easily be covered up when reproducing the document and that any such designation "was a joke." CW3 stated she/he implemented the attempted internal control of watermarking on her/his

own initiative because she/he was very uncomfortable to be in the role of Training Manager while being asked by Meyers to execute the Company's off-label marketing strategy for Viread through the dissemination of off-label data to the sales team.

159. CW5 stated that although the training department watermarked some of the promotional materials as being "not-for-promotional" use, this attempted internal control was circumvented throughout the Class Period. In particular, CW5 stated there were "poster books" of study abstracts and updates pertaining to Viread that Gilead prepared for circulation at major medical conferences. The "poster books" consisted of spiral bound notebooks containing Viread study updates, which were approved by the Company's Medical Affair's team and Statisticians. These "poster books" were distributed to physicians at the conferences and did not contain any markings indicating the documents were confidential or that they should not be used for promotional purposes. CW5 stated the Gilead Regional Directors and Therapeutic Specialists had access to these "poster books" and used them to promote Viread for off-label indications. As such, even though CW3 and CW5 attempted to implement certain internal controls to minimize off-label marketing (such as watermarking), these controls were easily and often circumvented because of the Therapeutic Specialists' ability to obtain clean copies of the same documents.

160. More specifically, CW5 stated that the "poster books" used by the Therapeutic Specialists during the Class Period contained abstracts from Study 903, such as week-96 data from Study 903. CW5 stated Therapeutic Specialists were trained by Gilead on how to use the data in the "poster books." According to CW5, the "good" sales representatives at Gilead during the Class Period had the Study 903 data (*i.e.*, off-label data on use of Gilead in treatment naïve HIV patients), and knew how to use it.

161. CW5 stated the Therapeutic Specialists utilized the "poster books" in role-playing as part of Gilead's training process. In this regard, CW5 stated that the HIV Therapeutic Specialists were not only provided with the requisite materials to market Viread off-label during the Class Period, but were also training on how to use the off-label study data in discussions with doctors. As an example, CW5 noted the HIV sales force was trained to ask leading questions, or to ask questions that would prompt the physicians on which they were calling to ask about off-label indications for

Viread. One such type of lead question that the HIV Therapeutic Specialists were trained to ask physicians was, "What kind of things do you do for your patients who are infected with Hepatitis B?" This question typically prompted the physician to ask about whether Viread could be used to treat Hepatitis B. CW5 stated the Viread sales force would then answer the physician's question using off-label data showing Viread to be an effective treatment for Hepatitis B.

162. CW3 reiterated that at Gilead, there was an obvious, covert off-label marketing strategy, whereby the Therapeutic Specialists were able to use off-label materials to promote and sell Viread. The emphasis at Gilead was on attaining sales goals, even though attainment of those goals meant the Therapeutic Specialists would engage in off-label marketing of the drug.

163. For example, CW3 stated there was an initial push, following the launch of Viread in 2001, to market Viread to the practitioners with an experienced patient base. These practitioners were an easy sell for the Gilead sales force. Sales of Viread began to level off, however, around the time CW3 was promoted to the Manager of Training in late 2002, and in the months prior to the Class Period. She/he stated that towards the end of 2002, the Company's internal sales goals became unrealistic, and in order for the Company's sales force to meet the increasingly unrealistic goals, the Therapeutic Specialists had to have a broader reach. This broader reach meant expanding promotional activities beyond the easy sales and reaching beyond the experienced patient market to off-label areas.

C. Defendants' False Promotional Practices Continue in 2003, and into the Class Period

164. On February 17, 2003, Gilead held a national meeting in Orlando, Florida. While at the meeting, CW1 and CW2 attended presentations concerning off-label information on Study 903 and Study 907 by Meredith, Gilead's Marketing Director, and Linda Cherry ("Cherry"), Gilead's Associate Marketing Manager. The information was presented to the sales staff in the form of key points from the off-label studies. Presenters Meredith and Cherry instructed CW1, CW2, and other members of the sales and marketing team to utilize the off-label key points to push their sales of Viread. CW1 recalled the instructions being less overt than in the past, but that when the sales teams met in smaller groups, the off-label marketing instructions were much more direct.

165. According to CW1 and CW2, Defendants Martin, Milligan, Bischofberger, Lee, and Perry, among others, were in the room when these instructions were given.

166. As described above, CW5 recalled that in the months prior to April 2003, Gilead had been losing ground on Viread sales. As such, a "re-launch" of Viread was necessary, and a planned, executed off-label strategy was required to make up this lost ground. As detailed in the April 2003 slide in question, at least part of the off-label marketing strategy for Viread entailed marketing Viread for patients co-infected with Hepatitis B, including promoting Viread as a treatment for Hepatitis B to gastroenterologists who treated HIV-infected patients. This strategy was facilitated by the Gilead Sales Analytics team, including gastroenterologists on the marketing lists for the Company's HIV Therapeutic Specialists. CW5 recalled that Dr. Cazen was one particular gastroenterologist in the San Francisco, California area who treated co-infected patients and to whom Gilead marketed Viread as a treatment for Hepatitis B during the Class Period.

167. In May 2003, CW2 was required to attend a meeting with Packard, one of Gilead's regional directors, at the Westin Hotel in downtown Atlanta. During this meeting, Packard criticized CW2 for his or her continued refusal to maximize his or her utilization of off-label materials to sell Viread. Thus, throughout CW2's career at Gilead, CW2 experienced first-hand Gilead's constant pressure to participate in its scheme to increase Viread sales through off-label marketing tactics.

168. CW3 recalled that in early 2003, the Company almost doubled its Viread sales force, adding at least 40 new Therapeutic Specialists in approximately mid-2003, and divided the eight existing sales territories into 12 regions. Further, there became a very obvious use of Viread in treatment naïve HIV patients. Although the increase in the number of Therapeutic Specialists should have increased sales, it should not have led to a change in the way Viread was being prescribed – not without off-label marketing. CW3 stated that beginning in the first half of 2003, there was a dramatic switch in numbers – or a notable change in the way Viread was being prescribed. CW3 stated that sales skyrocketed as a result of increased prescriptions to the treatment naïve patient market – for which Viread was not approved at the time. CW3 stated the treatment naïve market was extremely important for Gilead, but was difficult to penetrate for several reasons. First, Gilead did not have approval for a treatment naïve indication until late 2003. Second, practitioners would

typically want to test out Viread in experienced patients before prescribing it to treatment naïve patients. To accomplish this, Therapeutic Specialists marketed Viread as having a better safety profile than was indicated on the Package Labeling and marketed it as being as having no side effects.

169. CW3 estimated that prior to and during the Class Period, the segmentation of HIV patients was approximately 60% experienced patients, 30% naïve patients, and 10% salvage patients. Although the experienced segment of the market was larger, it was a more limited market niche, and represented easy sales for Gilead because experienced patients often developed mutations and resistance profiles that required practitioners to try other treatments. In other words, experienced patients were more likely to switch from using Viread to another drug in a shorter period of time than treatment naïve patients. The naïve market niche was more difficult to penetrate, but very important to Gilead and the growth of sales and market share pertaining to Viread. CW6 confirmed Viread sales representatives sold the drug as a first line therapy to treatment naïve patients "all the time" and that if they did not do so, they would be fired.

170. Penetrating the treatment naïve market is where Defendants' off-label marketing scheme came into play, and the Company used its training department as the sacrificial lamb to get more off-label information to the sales representatives about off-label indications for Viread, including favorable study results regarding the naïve indication. Moreover, despite CW3's attempts to implement her/his own controls in the distribution of off-label training materials, those controls faced stiff objections and were circumvented. Thus, off-label sales to the treatment naïve market skyrocketed. Indeed, CW6 was provided with off-label promotional materials to push Viread sales to the treatment naïve market, and estimated that ***at least 70%*** of her/his Viread sales were for off-label, treatment naïve use. CW6 stated the Company was pushing sales to treatment naïve patients because if Gilead got Viread to a treatment naïve patient, that patient was likely to take Viread for a very long time. In other words, access to the off-label treatment naïve market meant not only increased prescriptions, but increased renewals of those prescriptions for a period of many, many years.

171. Similarly, CW5 recalled there was definitely a drive within the Company to get doctors to prescribe Viread to treatment naïve HIV patients, prior to its approval for such use, during the Class Period. CW5 stated this was done as a means to rejuvenate the growth in sales of Viread. For example, CW5 stated the entire Therapeutic Specialist team was aware that the Study 903 data (on Viread's use in treatment naïve patients) was coming down the pipeline. CW5 stated that Gilead had to expand the scope of indications to include promoting Viread for off-label purposes in order to continue to gain market share and increase sales during the Class Period.

172. On June 23-27, 2003, CW2 attended a Gilead national meeting in San Francisco (the "San Francisco National Meeting") during which Gilead continued to instruct its sales staff on how to effectively use off-label materials to market Viread. Specifically, Gilead presenters instructed Gilead's sales staff, including CW2, on how to overcome the following four objections that potential customers raise regarding Viread: (1) "So Viread is now causing renal problems . . . I knew this would happen"; (2) "I am concerned about my NRTI options when my patients fail Viread"; (3) "I don't believe in qd regimens"; and (4) "My patients tolerate Zerit and I don't see the lipoatrophy develop in them."

173. In order to combat these objections, during the San Francisco National Meeting, Gilead provided its sales staff, including CW2, with a memorandum which included off-label talking points to be utilized in order to convince potential customers to look past these objections and purchase Viread (the "Off-Label Talking Points"). *See* Exhibit E attached hereto (a true and correct copy of the Off-Label Talking Points).

174. On CW2's information and belief, Meyers and Rich were present in the room at the San Francisco National Meeting when Gilead's presenters provided the sales staff, including CW2, with the Off-Label Talking Points. Further, on CW2's information and belief, Inouye and Defendants Martin, Milligan, Perry, and Lee, were present at the meeting (which was attended by all Medical Science Liaisons, Regional Directors, and National Account Managers) although they were not physically present in the room for the distribution of the Off-Label Talking Points.

175. CW2's knowledge and belief of Defendants' scienter is further supported by her/his knowledge of Gilead's standard protocol regarding preparation for regional and national meetings.

176. According to CW2, it was standard practice for all of Gilead's Regional Directors, prior to each national and regional meeting, to travel to Gilead's corporate headquarters in Foster City, California to meet with Gilead's senior management. During these meetings, which included, at various times, Defendants Martin and Perry, as well as Meyers, Weisbrich, Rich, and Helen Harris, the Regional Director of the Mid-Atlantic Region, Gilead's senior management would instruct Gilead's Regional Directors on what training was to be provided to Gilead's sales staff, including training on the use of off-label marketing materials.

177. Just like it did on a daily basis ever since Viread's approval in October 2001, as well as in December 2001, in the Second Quarter 2003 Gilead continued to minimize important risk information (including failing to disclose potentially fatal risks) and broaden the indication for Viread. This time, Gilead's improper and illegal campaign of lies led the FDA, through the DDMAC, to issue a warning letter.

178. On March 31-April 2, 2003, during the 15th National HIV/AIDS Update Conference in Miami, Florida, Gilead made additional off-label oral representations concerning Viread – this time to an FDA employee who was monitoring sales practices -- which minimized important risk information (including potentially fatal risks) and broadened the indication for Viread. As a result, on July 29, 2003, Second Quarter 2003 – the beginning of the Class Period – the FDA issued a warning letter to Gilead (the "FDA Warning Letter"). *See* Exhibit F attached hereto (a true and correct copy of the FDA Warning Letter).

179. According to the FDA's website and the FDA's Regulatory Procedures Manual, warning letters such as this are written communications from the FDA's DDMAC, to a company notifying the company that the DDMAC considers one or more promotional pieces or practices to be illegal. If the company does not take appropriate and prompt action to correct the violation, as requested in the warning letter, there may be further enforcement actions without further notice. Warning letters are issued by the DDMAC Division Director and receive concurrence from appropriate officials in the Center for Drug Evaluation and Research. A warning letter is much more serious than an untitled letter.

180. The FDA Warning Letter, issued during the Class Period and addressed to defendant Martin, stated that Gilead's illegal acts were "particularly troubling because the more than 1,500 attendees of [the 15th National HIV/AIDS Update Conference] included social workers, AIDS educators, and patients with HIV/AIDS."

181. As stated in the FDA Warning Letter, Gilead's lies were so outrageous that Gilead had created a new "intended use" for Viread, causing it to be misbranded.

182. According to the FDA Warning Letter, Gilead's ***repeated*** omissions and misrepresentations regarding Viread caused "significant public health and safety concerns," and led the FDA to require Gilead to respond with a plan to address the "repetitive promotional activities."

183. Defendants either specifically directed Gilead's sales force to engage in the fraudulent, misleading, and illegal promotional and marketing activities identified in the FDA Warning Letter or, at the very least, knew of the improper and illegal promotional and marketing activities but allowed them to take place.

184. In response to Gilead's repeated misconduct, the DDMAC requested in the FDA Warning Letter that Gilead take "action to disseminate accurate and complete information to the audience(s)" that received the misleading Viread promotional information. Thus, on November 7, 2003, Defendant Martin purported to write an open letter to all attendees of the 15th National HIV/AIDS Update Conference in Miami, Florida, entitled "IMPORTANT CORRECTION OF DRUG INFORMATION" (the "Correction Letter"). *See* Exhibit G attached hereto (a true and correct copy of the Correction Letter).

185. In the Correction Letter, Defendant Martin stated that the DDMAC instructed Gilead to contact conference attendees (there were over 1,500) because of misleading oral statements Gilead made in the promotion of Viread. The purpose of the Correction Letter was to provide "accurate information about Viread and [to correct] certain information as cited in the Warning Letter."

186. More specifically and contrary to what Gilead represented at the conference, Defendant Martin described how Viread: (1) does indeed have serious, potentially fatal, side effects; (2) is a "nucleotide," but belongs to the same class of drugs as "nucleosides"; (3) is a nucleotide, but that fact does not make it better or safer than other HIV drugs and does not make it more potent with

fewer side effects (an important clinical distinction the FDA determined Gilead failed to make); (4) is approved only for use in combination with other anti-HIV medicines to treat people with HIV-1 infection; and (5) has not been proven to lower cholesterol levels.

187. As indicated by the Confidential Witnesses, Defendant Martin and the other Defendants knew, prior to the Correction Letter, that Gilead's sales and marketing team was consistently instructed and trained to market Viread with off-label information that, among other things, misrepresented Viread's safety profile by minimizing critical risk information, illegally promoted Viread as a first-line therapy for treatment naïve patients, and illegally promoted Viread as a treatment for Hepatitis B-infected patients.

188. As a result of the activities identified, criticized, and rejected in the FDA Warning Letter as well as the consistent promotion of Viread by way of off-label information, Gilead caused a substantial increase in its sales of Viread during Second Quarter 2003. CW1 and CW2 state that 75% to 95% of Viread sales, including sales during the Class period, were caused by off-label marketing.

189. According to CW2 and CW5, the FDA Warning Letter was a result of comments made by Augustino "Tino" Quintero, one of Gilead's Therapeutic Specialists, at the 15th National HIV/AIDS Update Conference in Miami, Florida. In accordance with Gilead's sales force training, Quintero utilized off-label information when responding to inquiries regarding Viread. Unfortunately for Gilead, the questions Quintero was asked were posed by FDA representatives who were attending the conference specifically to monitor Gilead's sales and marketing tactics.

190. Amazingly, but not surprisingly, Gilead did not fire Quintero for making the off-label comments that he was taught to make by Gilead. Instead, subsequent to making those comments and subsequent to the issuance of the FDA Warning Letter, Gilead rewarded Quintero with membership in Gilead's "President's Club," a distinction reserved for Gilead's top sales producers. According to CW5, Quintero remains employed by Gilead, which would be impossible at other companies where off-label sales are grounds for termination.

191. CW1's and CW2's accounts of the numerous meetings and presentations attended by them, including national and regional meetings, provide a telling and disturbing snapshot of Gilead's

sales practices and culture. All of the Confidential Witnesses' collective accounts of the significant details of Gilead's systematic presentation of off-label information to market Viread, and the stunning impact the use of that off-label information had on Viread sales, are virtually identical. At regional meetings, Gilead encouraged CW1, CW2, and other sales team members to aggressively sell Viread with off-label information. At national meetings, Gilead instructed its entire Viread sales force to market Viread with off-label studies and information that were deliberately provided by the Company's training department, as described by CW3 and CW5. Indeed, CW1 and CW2's detailed accounts of the national meetings strongly suggest that their experiences at Gilead were neither atypical nor uncommon; rather, their experiences were the norm. Gilead's sales people were required to and did utilize off-label marketing materials to sell Viread. Both CW1 and CW2 discussed the use of off-label marketing with other members of Gilead's sales force who confirmed their use of off-label information and the fact that their use of such information stimulated sales. It is, therefore, reasonable to infer that 75% to 95% of Viread sales during the Class Period were caused by off-label marketing as the impact is equally applicable to other Gilead salespeople as it is to CW1, CW2, and CW6.

192. At the various meetings described above, Gilead also provided its Viread sales force, including the Confidential Witnesses described herein, with numerous slides, posters, and presentation materials that came directly from the Company's training department. These posters and presentations detailed the off-label clinical information presented at a given meeting. Typically, pharmaceutical manufacturers stamp all such materials with a designation that they should not be used in sales and marketing presentations – that they contain clinical research not approved by the FDA. Defendants did not do this and circumvented CW3's attempts to do this precisely because they intended that these off-label materials would be used to market Viread. As described by CW6, any attempt to restrict use of these off-label materials was a "joke." CW6 also had access to PowerPoint presentations from the Company's Medical Science Liaisons, and the slides could be and were used in sales calls. Based on repeated directives to use off-label data to sell Viread, CW1 recalls that there was not one day that went by during the course of CW1's selling of Viread that CW1 was not utilizing data that was not yet approved by the FDA.

193. According to CW1 and CW2, often the posters would be distributed with an accompanying memorandum describing them as off-label; however, the posters themselves would completely lack any off-label designation. CW6 recalled that if the off-label materials did have any special designation, it was stamped on the bottom or in the margins, such that the designations could easily be eliminated during photocopying. This would enable Gilead's sales and marketing team members to use the information in sales presentations without the customer realizing that he or she was seeing off-label information. Therefore, as it did in national and regional meetings, Gilead was able to continue its "wink and nod" tactics even with off-label posters. As recounted by CW3, the Company's training department was tasked with disseminating off-label materials to the sales force.

D. Defendants' Off-Label Promotion Increased Sales of Viread

194. At all times relevant to the Class Period, Defendants' continued use of off-label marketing of Viread worked, causing physicians to prescribe more Viread. In addition, Defendants' off-label marketing caused physicians to prescribe Viread for purposes other than those approved by the FDA. Thus, off-label marketing had its intended impact – Defendants significantly increased Viread sales.

195. CW3 stated there was definitely a "wink and nod" strategy to promote Viread off-label both before and during the Class Period. This strategy was driven by the desire for increased growth in the sales of Viread, as well as the premise that the HIV market was centered on a "dynamic disease," for which new data was regularly emerging. And, as CW3 confirmed, Gilead's strategy to market for off-label indications followed the tone from the top, as set by Defendant Martin, who routinely spoke about Viread off-label. Through following Martin's lead and observing Martin's off-label promotion of Viread, the Therapeutic Specialists learned that such behavior was the acceptable and expected practice.

196. In the Washington state region to which CW3 was assigned when she/he was a Therapeutic Specialist, Martin often spoke to doctors with practices that entailed the treatment of 200 to 500 HIV patients and key opinion leaders to promote Viread for off-label indications. CW3 explained there were doctors who were heads of large HIV departments or who led regional medical centers, and who typically would not agree to see a Therapeutic Specialist. These more high profile

HIV practitioners, however, would allow appointments from a Gilead Medical Science Liaison or Martin. When a Medical Science Liaison or Martin visited the more high profile HIV practitioners, the nature of the visit was typically a sales call and CW3 stated that off-label information was often disseminated in such sales calls.

197. While Martin's observed off-label promotion of Viread occurred prior to the start of the Class Period, CW3 confirmed the Company's off-label promotion of Viread continued into the Class Period. As set forth above, during the Class Period, CW3 was directed to write-up and develop training materials for the sales force that included off-label details regarding Viread. CW3 received a clear message from Meyers to include such information in the training materials for incumbent and incoming Therapeutic Specialists.

198. According to CW1, approximately 50-60% of HIV patients were included in an initial therapy group of patients who were using an HIV drug regimen for the first time. Another 30-40% were part of a second therapy group of patients who were making their first switch to a different HIV treatment regimen. Only approximately 20% of patients (*i.e.*, those who were not part of the initial or second therapy groups) were in a rescue situation, looking for a drug that would control their viral load after the virus developed a resistance to other combinations of HIV drug therapies.

199. In other words, as a result of the manner in which Viread was approved by the FDA, roughly 60% of the available HIV patient pool was unavailable to Defendants. However, Viread was aggressively and illegally marketed in order to open up the maximum potential patient pool. As a result, Viread was prescribed off-label to these patients. Therefore, according to several Confidential Witnesses, including CW1, Defendants instructed Viread sales representatives to promote studies (*i.e.*, Study 903) on the effect of Viread on initial or first-line therapy patients to foster increased sales. Defendants further publicized new studies on Viread and provided them to their sales and marketing staff in an attempt to change physicians' views on the drug and achieve sales beyond the patients authorized by the FDA.

200. Defendants' off-label campaign succeeded. CW1 sold approximately $3 million of Viread during his tenure at Gilead. According to CW1, approximately 85% to 95% of all of CW1's Viread sales arose from off-label promotion. In fact, CW1 did not have a single sales contact where

off-label information was not used to market Viread. According to CW1, the Company provided so much off-label data and was so forceful in instructing sales representatives to utilize off-label information that off-label information was the cornerstone of Gilead's Viread marketing efforts. This unequivocal sentiment was echoed by several other Confidential Witnesses. According to many Confidential Witnesses, off-label marketing took three forms: (1) marketing to HIV patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial therapy for HIV infection; and (3) marketing against Viread's safety profile.

201. CW2's experiences mirror CW1's and CW2 corroborates CW1's analysis of the material impact of off-label marketing on Gilead's sales of Viread. To be sure, CW2's Viread sales were also based, in very large measure, on off-label marketing. CW2's sales analysis can be divided into two parts: before and after Georgia, CW2's territory, added Viread to its formulary list for the federal AIDS Drug Assistance Program ("ADAP") system.

202. According to the U.S. Department of Health and Human Services, ADAP provides medications for the treatment of HIV disease. The program is funded through Title II of the Ryan White CARE Act, which provides grants to States and Territories. Through ADAP, grants are awarded to all 50 States. Specifically, Congress earmarks funds that must be used for ADAP. The ADAP "earmark" has increased more than 1,000 percent over the past five years, from $52 million in 1996 to $639 million in 2002. But, total ADAP spending is even higher, since State ADAPs also receive money from their respective States, other CARE Act programs, and through cost-savings strategies.

203. Approximately 128,078 people received medications through ADAP in 2000. None had adequate health insurance or the financial resources necessary to cover the cost of medications. On average, 73,000 clients are served each month. The ADAP in each State and Territory is unique in that it decides which medications will be included in its formulary, and how those medications will be distributed. Each State and Territory establishes its own eligibility criteria. All require that individuals document their HIV status. Fifteen States have established income eligibility at 200% or less of the Federal Poverty Level ("FPL"). Nationally, more than 80% of ADAP clients have incomes at 200 percent or less of the FPL. *See* http://hab.hrsa.gov/programs/factsheets/adap1.htm.